Complete Summary

GUIDELINE TITLE

ACR Appropriateness Criteria™ for needle biopsy in the thorax.

BIBLIOGRAPHIC SOURCE(S)

Van Moore A, Levy JM, Duszak RL, Akins EW, Bakal CW, Denny DF, Martin LG, Pentecost MJ, Roberts AC, Vogelzang RL, Kent KC, Perler BA, Resnick MI, Richie J. Needle biopsy in the thorax. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun;215(Suppl):1029-40. [44 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Primary lung carcinoma

GUIDELINE CATEGORY

Diagnosis
Management

CLINICAL SPECIALTY

Oncology
Pulmonary Medicine
Radiology

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of using needle biopsy in the thorax to:

- Differentiate between primary carcinoma in the lung neoplasm from benign disease, metastatic malignancy, or other unusual pulmonary neoplasm
- Stage and manage the disease

TARGET POPULATION

Patients with suspected primary lung carcinoma

INTERVENTIONS AND PRACTICES CONSIDERED

Needle biopsy

MAJOR OUTCOMES CONSIDERED

- Overall survival
- Quality of life
- Morbidity or mortality associated with primary lung carcinoma
- Improved care

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of recent peer-reviewed medical journals, primarily using the National Library of Medicine's MEDLINE database. The developer identified and collected the major applicable articles.

NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Delphi Method)
Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed to reach agreement in the formulation of the Appropriateness Criteria. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty (80) percent agreement is considered a consensus. If consensus cannot be reached by this method, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria and the Chair of the American College of Radiology Board of Chancellors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria™

Interventional Procedure: Needle Biopsy of Pulmonary Nodule

Variant 1: Solitary pulmonary mass.

Presentation/Signs/Symptoms	Appropriateness Rating	Comments
History		
• Significant tobacco abuse	8	
• Previous granulomatous disease	8	
• Prior malignancy	8	
• HIV + serology	7	
• Negative for previous malignancy	7	
• Severe pulmonary hypertension	4	
• Prior pneumonectomy	4	
Physical Examination		

• Patient unable to cooperate with procedure	2	
Laboratory Findings		
• Negative cultures in a septic patient	7	
• Correctable coagulopathy	7	
• Severe pulmonary function compromise	4	
• Non-correctable coagulopathy	2	
Imaging Examination		
• No hilar/mediastinal lymphadenopathy by computed tomography/magnetic resonance imaging (CT/MRI)	8	
• Contralateral mediastinal/hilar nodes	8	
• Ipsilateral hilar and peribronchial nodes	7	
• Ipsilateral mediastinal nodes/subcarinal nodes	7	
• Blebs in needle path	4	
• Scalene/supraclavicular lymph nodes	3	
• Extrathoracic distal metastasis/masses approachable by needle	2	

aspiration biopsy (NAB)		
• Mass calcified by CT/conventional radiography	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 2: Multiple pulmonary masses/nodules.

Presentation/Signs/Symptoms	Appropriateness Rating	Comments
History		
• Significant tobacco abuse	8	
• Previous granulomatous disease	8	
• Prior malignancy	8	
• Negative for previous malignancy	8	
• HIV + serology	8	
• Prior pneumonectomy	4	
• Severe pulmonary hypertension	4	
Physical Examination		
• Patient unable to cooperate with procedure	2	

Laboratory Findings		
• Correctable coagulopathy	8	
• Negative cultures in a septic patient	8	
• Severe pulmonary function compromise	4	
• Non-correctable coagulopathy	2	
Imaging Examination		
• No hilar/mediastinal lymphadenopathy by CT/MRI	8	
• Ipsilateral hilar and peribronchial nodes	7	
• Ipsilateral mediastinal nodes/subcarinal nodes	7	
• Blebs in needle path	4	
• Mass calcified by CT/conventional radiography	2	
• Scalene/supraclavicular lymph nodes	2	
• Extrathoracic distal metastasis/masses approachable by NAB	2	
• Contralateral mediastinal/hilar nodes	No Consensus	

Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate

Variant 3: No detectable pulmonary mass.

Presentation/Signs/Symptoms	Appropriateness Rating	Comments
History		
• Significant tobacco abuse	8	
• Previous granulomatous disease	8	
• Prior malignancy	8	
• HIV + serology	8	
• Negative for previous malignancy	8	
• Severe pulmonary hypertension	6	
• Prior pneumonectomy	5	
Physical Examination		
• Patient unable to cooperate with procedure	2	
Laboratory Findings		
• Correctable coagulopathy	7	
• Severe pulmonary function	4	

compromise		
• Non-correctable coagulopathy	2	
Imaging Examination		
• Hilar/mediastinal lymphadenopathy by CT/MRI	8	
• Blebs in needle path	4	
• Extrathoracic distal metastasis/masses approachable by NAB	2	
• Scalene/supraclavicular lymph nodes	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 4: Pulmonary mass/masses.

Presentation/Signs/Symptoms	Appropriateness Rating	Comments
History		
• Significant tobacco abuse	8	
• Previous granulomatous disease	8	
• Prior malignancy	8	
• HIV + positive serology	8	

• Negative for previous malignancy	8	
• Prior pneumonectomy	5	
• Severe pulmonary hypertension	4	
Physical Examination		
• Patient unable to cooperate with procedure	2	
Laboratory Findings		
• Correctable coagulopathy	7	
• Severe pulmonary function compromise	5	
• Non-correctable coagulopathy	2	
Imaging Examination		
• Ipsilateral hilar nodes/peribronchial nodes	8	
• Ipsilateral mediastinal nodes/subcarinal nodes	8	
• Contralateral mediastinal nodes/hilar nodes	8	
• Blebs in needle path	4	
• Scalene/supraclavicular lymph nodes	2	
• Extrathoracic distal	2	

metastasis/masses approachable by NAB		
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 5: No detectable pulmonary mass.

Presentation/Signs/Symptoms	Appropriateness Rating	Comments
History		
• Significant tobacco abuse	8	
• Previous granulomatous disease	8	
• Prior malignancy	8	
• Negative for previous malignancy	8	
• HIV + positive serology	7	
• Prior pneumonectomy	6	
• Severe pulmonary hypertension	4	
Physical Examination		
• Patient unable to cooperate with procedure	2	
Laboratory Findings		

• Correctable coagulopathy	7	
• Severe pulmonary function compromise	4	
• Negative cultures in a septic patient	4	
• Non-correctable coagulopathy	2	
Imaging Examination		
• Scalene/supraclavicular lymph nodes	2	
• Extrathoracic distal metastasis/masses approachable by NAB	2	
• Blebs in needle path	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 6: Pulmonary mass/masses.

Presentation/Signs/Symptoms	Appropriateness Rating	Comments
History		
• Significant tobacco abuse	8	
• Previous granulomatous disease	8	

• Prior malignancy	8	
• HIV + positive serology	8	
• Negative for previous malignancy	8	
• Severe pulmonary hypertension	6	
• Prior pneumonectomy	6	
Physical Examination		
• Patient unable to cooperate with procedure	2	
Laboratory Findings		
• Correctable coagulopathy	8	
• Severe pulmonary function compromise	4	
• Negative cultures in a septic patient	4	
• Non-correctable coagulopathy	2	
Imaging Examination		
• Ipsilateral hilar nodes/ipsilateral peribronchial nodes	8	
• Ipsilateral mediastinal nodes/subcarinal nodes	8	
• Contralateral	8	

mediastinal/contralateral hilar nodes		
• Scalene/supraclavicular lymph nodes	2	
• Extrathoracic distal metastasis/masses approachable by NAB	2	
• Blebs in needle path	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Summary

There are numerous etiologies for the solitary pulmonary mass. With primary lung carcinoma representing only 21 to 38 percent of these lesions and with 5 to 15 percent of primary pulmonary neoplasms representing small cell carcinomas, needle biopsy for diagnosis is appropriate to diagnose the larger population of benign lesions, metastatic lesions, and malignant lesions other than non-small-cell lung carcinoma (NSCLC). This is not to say that thoracotomy or thoracoscopy do not have a role in the diagnosis of the solitary pulmonary mass. The precise roles of these modalities in this diagnostic setting are in evolution. Needle biopsy has a high level of diagnostic accuracy; has favorable economic, morbidity and mortality comparisons and it can be routinely performed on an outpatient basis. In the current cost conscious medical economic climate, the use of thoracotomy or thoracoscopy to diagnose a benign or metastatic pulmonary mass may be counterproductive. Needle biopsy of mediastinal or hilar lymphadenopathy in the setting of a primary pulmonary mass assists in the diagnosis as well as the clinical staging of the non-small-cell lung carcinoma so that appropriate therapeutic regimen can be considered. Thin needle aspiration biopsy and cutting needle biopsy in a variety of non-lymphoproliferative primary mediastinal processes also have high diagnostic accuracy's and low morbidity.

Fine needle aspiration biopsy diagnostic rates in primary, non-diagnosed lymphoma are low, even when newer immunoperoxidase staining techniques are applied. When larger cutting needles cannot be used to obtain the diagnostic material, open biopsy has a higher diagnostic yield. The diagnostic accuracy of thin needle aspiration biopsy (TNAB) in the setting of recurrent lymphoma is very high, especially when multiple needle passes are made to obtain diagnostic material. Thin needle aspiration biopsy for culture in the diagnosis of inflammatory masses/infiltrates is a means of obtaining material when more

traditional methods for obtaining culture material are not productive. The diagnostic yield is high in immunocompromised patients, both human immunodeficiency virus negative and human immunodeficiency virus positive. These yields should be comparable for difficult to diagnose non-immunocompromised patients.

CLINICAL ALGORITHM(S)

Algorithms were not developed from criteria guidelines.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosing, staging, and management of primary lung carcinoma with needle biopsy in the thorax may improve overall survival, care, and quality of life.

POTENTIAL HARMS

Complications from transthoracic needle biopsy are pneumothorax (from 1.3 to 2.7%) and mild hemoptysis (from 2.7 to 8%) When core cutting needles have been employed the pneumothorax rate is reported to range from 34% to as high as 54%. The need for insertion of a thoracostomy tube ranges from 3.6% to 10%. Most pneumothoraces do not require intervention and resolve with time. When a larger pneumothorax is present a majority (70%) can be managed successfully by simple aspiration of the air. The vast majority of post-thin needle aspiration biopsy pneumothoraces that require treatment can be managed by small bore thoracostomy tube inserted percutaneously. No reported deaths are noted in several series containing over 1500 patients receiving needle biopsies reviewed. Death as a complication of thin needle aspiration biopsy is a rare event.

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindications to needle aspiration biopsy are all relative. No contraindication is absolute. Relative contraindications include known severely compromised pulmonary function, known coagulopathy, known severe pulmonary hypertension, a patient who is unable to cooperate during the biopsy, blebs in the needle approach path and previous contralateral pneumonectomy.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Van Moore A, Levy JM, Duszak RL, Akins EW, Bakal CW, Denny DF, Martin LG, Pentecost MJ, Roberts AC, Vogelzang RL, Kent KC, Perler BA, Resnick MI, Richie J. Needle biopsy in the thorax. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun;215(Suppl):1029-40. [44 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 (revised 1999)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these American College of Radiology Appropriateness Criteria™.

GUIDELINE COMMITTEE

American College of Radiology Appropriateness Criteria™ Committee, Expert Panel on Interventional Radiology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Arl Van Moore, Jr., MD; Jonathan M. Levy, MD; Richard L. Duszak, Jr., MD; E. William Akins, MD; Curtis W. Bakal, MD; Donald F. Denny, Jr., MD; Louis G. Martin, MD; Michael J. Pentecost, MD; Anne C. Roberts, MD; Robert L. Vogelzang, MD; K. Craig Kent, MD; Bruce A. Perler, MD; Martin I. Resnick, MD; Jerome Richie, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline. It is a revision of a previously issued version (Appropriateness criteria for needle biopsy in the thorax. Reston [VA]: American College of Radiology [ACR]; 1996. 22 p.).

An update is not in progress at this time.

The American College of Radiology Appropriateness Criteria™ are reviewed after five years, if not sooner, depending upon introduction of new and highly significant scientific evidence. The next review date for this topic is 2004.

GUIDELINE AVAILABILITY

Electronic copies: Available (in Portable Document Format [PDF]) from the American College of Radiology (ACR) Web site.

Print copies: Available from ACR, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on March 28, 2002. The information was verified by the guideline developer on May 28, 2002.

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